

**SUMMARY OF THE  
OPENING PLENARY MEETING  
DECEMBER 04, 2001**

The Opening Plenary of the National Environmental Laboratory Accreditation Program (NELAP) met on Tuesday, December 04, 2001 at 1:00 p.m. Eastern Daylight Time (EDT) as part of the Seventh NELAC Interim Meeting in Arlington, VA. The meeting was led by Board of Director Chairperson Jeanne Hankins of the USEPA/ORD. A list of participants is given in Attachment A. Participants presentations are given in Attachments B, C, and D. The purpose of the meeting was to discuss agenda items which follow.

**INTRODUCTION**

Ms. Hankins introduced herself and asked that each committee member introduce themselves and state their affiliation. She then introduced Jackie Sample, Laboratory Programs Manager of the US Navy as host to NELAC 7i. Ms. Sample welcomed attendees to the conference, and introduced Silky Labie, Co-Chairperson of the Board of Directors.

**OPENING PLENARY REMARKS BY SILKY LABIE**

The following is the presentation and opening remarks given by Ms. Silky Labie.

This has been an unusual meeting. Some of us have been here since Saturday, discussing some of the issues that I plan to mention.

For me, I seem to be continually changing roles. On Saturday and Sunday, I was a participant in critical discussions. On Monday and Tuesday morning, I was a student, taking advantage of one of the excellent courses offered at this meeting. Now I have become a listener and diagnostician – feeling the pulse of NELAC. Later this week, I will change hats again to become part of the assessment team that is evaluating EPA's application to become an accrediting authority. I feel a little like Dr. Jekyll or maybe it's Mr. Hyde, so if you see me off in a corner with glazed eyes and drooling a little bit, just let me know what day it is, and I will snap back into that role.

So much for my well-being. I have observed that past chairs use this time to set the stage for expectations. There is, however, a more important task for me to do and that is dispelling rumors, gossip and innuendos. And believe me, the electrons have been busy flying across the country with conjecture, theories and "he said/she said" stories. First of all, a little insight on the status of NELAC. We have spent the past 7 years being nurtured and guided by EPA. We are now in the somewhat rebellious teen-age years, and I can really relate especially when I catch myself acting and thinking like my teenage son. NELAC is at a crossroad. We need to think about what we want to be in the future. To that end, a number of key individuals in NELAC spent the weekend trying to determine what the future holds for us. Our tasks included discussing the rumors and realities, identifying and prioritizing critical challenges facing NELAC, and offering potential solutions. What I want to share with you are the rumors and the realities beginning with rumor number one. And this is a multiple choice quiz.

Ask yourself what you have heard about private sector participation. Is it:

A. participation be eliminated

- B. minimized
- C. deemed no longer necessary
- D. all of the above

Concerning EPA's role: It is that they are

- A. considering withdrawing support
- B. considering withdrawing funding
- C. all of the above

There are some pretty heady rumors that can make or break NELAC. Let's look at rumor two first. The reality is that while NELAC, as an organization, has contributed lots of time and assisted with some activities, EPA is the sole funding source for NELAC. Add to that the fact that there are some activities that neither NELAC, the conference, nor EPA can support. As supposedly equal partners, we need to ask ourselves what we can contribute toward the sustainability of NELAC's future. It is not that EPA will discontinue monetary or technical support, it's the simple fact that all the other stakeholders need to step up to the plate and help out.

There are a lot of activities associated with NELAC. Jeanne outlined a comprehensive list of activities that use EPA support and some that need doing. Many of us are only marginally aware of some of these tasks, but it's what makes NELAC and NELAP run smoothly. Over the weekend, we added another two: the need to have training and education for certain stakeholder groups, and the need to have what we have termed the NICE line – with apologies to RCRA and the MICE line. I hope we haven't infringed on any copyrights. Of these activities, four were identified as inherently EPA functions. Assuming the responsibility for the others is up for grabs.

### **Private Sector Participation: What is Really Happening?**

The reality is times change. In 1995 when NELAC first met, EPA laid out certain structural criteria that had to be met in order for NELAC to operate in the proposed relationship with EPA. The private sector could not be members but could be considered contributors. They could participate in committee meetings but any selection criteria for membership needed to be based on individual merits, rather than organizational representation. Consensus advice was prohibited, and the State and Federal Members voted on the standards.

Things changed just recently because of a legal ruling. In order to maintain the same relationship with EPA, the membership must be limited to state, federal and tribal officials. Any standard development or drafting must be done solely by this governmental group. The private sector may provide comments, but deliberations and debates on comments are limited to the state, federal or tribal membership. Finally, as always, consensus advice is prohibited. The critical differences are in developing standards, and limitations on interactions with the private sector.

The plain truth is that NELAC's success and NELAP's reality are due to the very meaningful partnerships that have developed. These partnerships have been based on trust, mutual respect, and a common vision.

Each of the participants during the weekend session recognized that without the support and input of the contributors, NELAP would not have 800 plus laboratories, and NELAC may still be sitting in someone's in box for review.

Furthermore, the continuing success is directly related to the input, support and participation of the non-governmental stakeholders.

### **What to Do?**

At first, the prognosis seemed very bleak. A small group of us that represented the major stakeholders, EPA, State, Industry and Laboratories, put our collective heads together and brainstormed for an hour on options. Some were eliminated because of fatal flaws. NELAC could become a Federal Advisory Committee. But as such, its role is strictly advisory – EPA could use or ignore recommendations. NELAC could become totally privatized, a situation that would lose the support of the States, because most states cannot recognize the authority of a private organization. Statutory authorization for NELAC through Congress could be requested. This however, would not guarantee permanency, and would add factors that none of the stakeholders could control. We could maintain the status quo, a position that is not acceptable to EPA. That doesn't leave very many options. The group said that as a last resort, NELAC could restrict membership and find ingenious ways of involving the non-governmental stakeholders. The option that seemed to best fit was a combination of a private-sector organization that worked hand-in-hand with NELAC and NELAP.

This is very rudimentary conceptual diagram – keep in mind we have no answers on details. The standard development body would be privatized. This means that all stakeholders are granted equal privileges of participation and voting. NELAC would become a strictly governmental organization. They would take the product of the standard development body, and adopt them as national standards. EPA would continue in its role of recognizing accrediting authorities, and the accrediting authorities would accredit laboratories. All those administrative functions that I displayed earlier would be assigned to one of the three groups.

### **The Benefits?**

There are many, and yes, there are concerns. But the pros far outweighed the cons. EPA costs could be reduced because many of the functions would be performed by the private organization. The private sector would definitely have an increased, far more definitive role in developing standards. It satisfies EPA's organizational concerns. It facilitates finding other sources of funding to supplement EPA contributions, it satisfies the States concerns since EPA will continue to play a major role for key issues. It essentially leaves NELAC and NELAP intact, which means little disruption in the current process. Best of all, it gets NELAC out of the standards development business, to allow more time to focus on other critical challenges.

It seems like a win-win situation. You will have several opportunities during the next 3½ days to learn more and to provide input. These include ELAB, which meets immediately after the plenary, Chapter 1, Program, Policy and Structure, and the Transition Committee meetings. This proposal is not set in stone, and I encourage you to think of and propose other options.

### **Report Card**

You remember that I talked about some : “C” words in Salt Lake City. I thought this would be a

good opportunity evaluate how well NELAC is doing.

- Cooperation – (A-) All sectors and groups within NELAC are cooperating to reach that common goal of a strong NELAC program.
- I give commitment a B- because I think we have lost a lot of the original new program energy, drive and momentum.
- Consistency – (B+) The AAs have been working diligently to minimize even the perception of inconsistencies between state programs.
- Communication – (We need some help) I don't think we are using the established lines of communication effectively, and we certainly are not looking for others.

On major committee issues – we have straight Bs with one incomplete, since we have not received a response from EPA on the PT data base issue. So in addition to considering all the other issues we have at this conference I would like you to think about.

### **Improving the Report Card.**

What can be done to improve external and internal communications?

- In light of restructuring, external communication is essential. First and foremost, we must acknowledge all contributions and to identify ways of actively involving more people in developing or revising standards.
- We need to identify new contacts and organizations and follow-through on involving them with NELAC.
- Let's take advantage of as much positive publicity as we can by making presentations at conferences, workshops and anyone who will listen. The more positive exposure NELAC has, the faster it will grow.
- Internally, we must encourage interaction between committees.
- And we need to revitalize processes to encourage other states and federal organizations to become accrediting authorities.

The accrediting authorities have worked long and hard on consistency. But we need more work.

- If a state is having internal discussions on standard interpretations, chances are that some of the other accrediting authorities have the same problem and
- We need to facilitate more interaction between the assessors – just how to accomplish this with limited travel funding will be the problem.
- Keep an open mind and be flexible with our solutions.

About commitment, please don't misunderstand my observation. I don't think that anyone here is less committed; it's just that I sense that we are losing the original momentum and energy. We need an energy boost.

- We must communicate our successes, for our benefit as well as others.

- We must emphasize the unique partnerships that have formed over the past decade and strive to maintain the rapport, trust and mutual respect that have resulted.
- We need new blood. In order to do that we will need to show that a new structure will strengthen the partnerships and demonstrate

NELAC is an open and fair process for all stakeholders and that the implementation of the standards enhance the ability to make informed environmental decisions.

I mentioned critical concerns. These are issues or problems that NELAC faces. Stay tuned. This will be discussed at 3:00 during the ELAB meeting.

### **Next Steps**

What do I see as our marching orders for NELAC 7i?

- We must concentrate on improvement – the standards, the system and communication.
- Don't jump to conclusions – consider the facts that I've presented, then be prepared to
- Offer Solutions
- Voice your concerns
- Provide input.

NELAC has encountered many obstacles in the past. And it seems that with everyone's help, support and dedication, we manage to beat seemingly insurmountable odds. This is a big mountain to climb, but I know that success lies in our future and together we can make it!

In a few minutes, it will be time to go to work. So get your thinking caps ready, be prepared to do some brainstorming, please let us you're your thoughts and ideas. Thank you

### **EPA ACTIVITIES ON LABORATORY QUALITY SYSTEMS**

Nancy W. Wentworth, Director of the Quality Staff Office of Environmental Information, proceeded with her presentation on EPA Activities on Laboratory Quality Systems. The key points discussed during her presentation include:

- Where are we?
- Why do we care?
- Where do we want to be?
- How will we get there?
- How will we know we are there?

The details of her presentation can be reviewed in Attachment C.

### **ACCREDITING AUTHORITY WORK GROUP REPORT**

Joe Aeillo of New Jersey Department of Environmental Protection - OQA, proceeded with his presentation on the Accrediting Authority Work Group Report. The key points discussed during his presentation include:

- Accrediting Authority Work Group as of December 2, 2001
- Issues Addressed and Forwarded to NELAC Standing Committees
- Issues Addressed and Policies Adopted

The details of his presentation can be reviewed in Attachment D.

#### **ADJOURNMENT**

Ms. Hankins thanked the attendees for coming and wished them a successful conference.

**PARTICIPANTS**  
**OPENING PLENARY MEETING**  
**DECEMBER 04, 2001**

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**OPENING PLENARY  
OPENING REMARKS BY SILKY LABIE**

**NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE  
SEVENTH INTERIM MEETING  
ARLINGTON, VA  
DECEMBER 4-7, 2001**





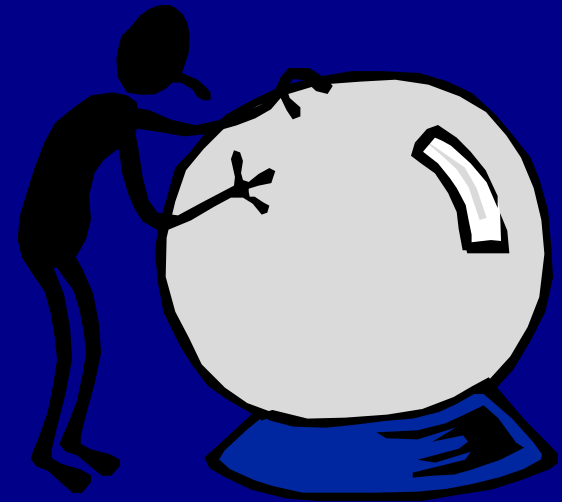
# NELAC 7i

Dispelling Rumors, Gossip  
Setting the Stage  
and Innuendos

# GROWING PAINS



# Future Visions



## ► Participants

- BoD , Chairs , ELAB , Transition Committee

## ► Tasks

- Rumors and Reality
- Identify & Prioritize Critical Challenges
- Identify Solutions

# **Rumor 1**

**Private Sector Participation is**

- a. Eliminated**
- b. Minimized**
- c. No longer necessary**
- d. All of the above**

# **Rumor #2**

**EPA is:**

- a. Withdrawing Support**
- b. Withdrawing funds**
- c. All of the above**

# **EPA's Role**

# Reality

- ▶ EPA is Sole Funding Source
- ▶ Activities that Neither NELAC nor EPA can Support

As Partners, What can Stakeholders  
Contribute?

# What Make NELAC Tick?

- ▶ Sponsor & Make Arrangements for NELAC meetings
- ▶ Coordinate Teleconference
- ▶ Scribe
- ▶ Standards Publication
- ▶ Maintain Other Documentation
- ▶ Maintain NELAC website
- ▶ Maintain NELAP database
- ▶ Evaluate & Recognize NELAP AAs
- ▶ Accreditate State & EPA laboratories
- ▶ Approve PTOBs
- ▶ Approve Laboratory Assessor Trainers
- ▶ Maintain PT database
- ▶ Conduct Needs Survey
- ▶ Training / Education
- ▶ NICE Line

# **Private Sector Participation**



# Reality

**1995**

- 1. Private Sector were “Contributors” not Members**
- 2. Selection Criteria Based on Individual Merits, not Organizational Representation**
- 3. Consensus Advice Prohibited But Deliberations Allowed**
- 4. State & Federal Members Voted**

**2001**

- |   |          |
|---|----------|
| <b>Federal, State &amp; Tribal Officials May be Members</b> | <b>1</b> |
| <b>Document Development only by Members</b>                 | <b>2</b> |
| <b>Private Sector May Provide Comments</b>                  | <b>3</b> |
| <b>Deliberations limited to Members</b>                     | <b>4</b> |
| <b>Consensus Advice Prohibited</b>                          | <b>5</b> |

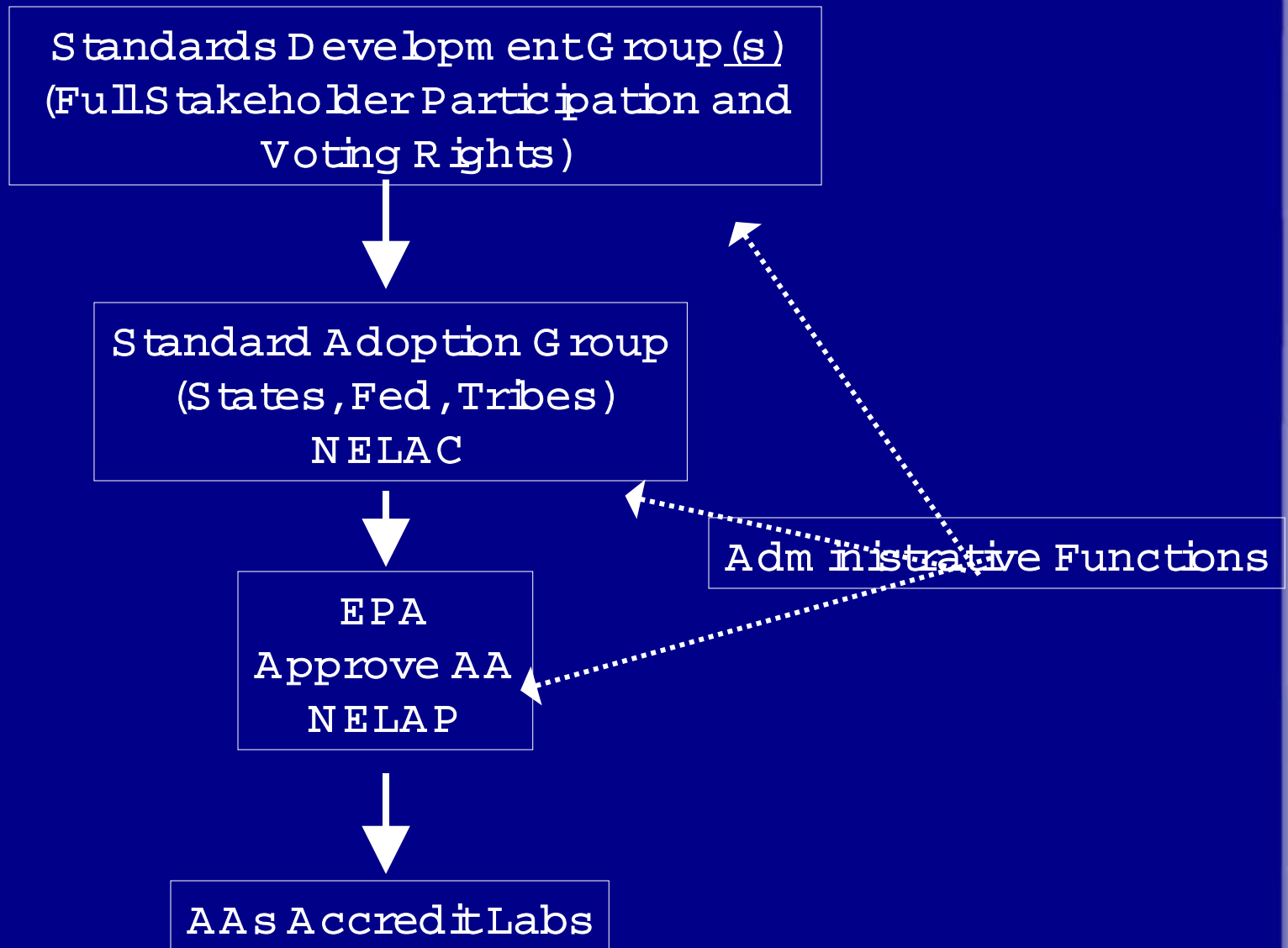
# Reality

- ▶ NELAC 's Success and NELAPs Reality are Due to
  - Meaningful Partnerships
    - Trust
    - Mutual Respect
    - Common Vision

**What to Do?**

# Options

1. NELAC=FACA
2. Total Privatization
3. Statutory Authorization for NELAC
4. Status Quo w /EPA Mgm tReview Policy
5. NELAC w /M em bership Restrictions
6. Independent Standard Development  
Body+NELAC+NELAP



# Benefits

- ▶ Reduced EPA Costs
- ▶ Increased Stakeholder Involvement
  - Equal Partnerships
- ▶ Opens Standard Development
- ▶ Satisfies EPA Concerns
- ▶ Facilitates Funding from Others
- ▶ Maintains EPA Role for Key Issues
- ▶ Preserves NELAC NELAP
- ▶ NELAC Focus can Concentrate On Critical Issues

# NELAC Report Card

C o o p e r a t i o n	A -
C o m m i t m e n t	B -
C o n s i s t e n c y	B +
C o m m u n i c a t i o n	B -

# NELAC Report Card

PBM S	B
ISO 17025 Conversion	B
Field Activities	B
On-Site Checklists	B
Mobile Labs	B
EPA Data Base	I





# Improving the Report Card Communication

## ► External

- Contributors and Volunteers
- Identify New Contacts and Follow-Up
- Identify Opportunities for Publicity

## ► Internal

- Encourage Intra-Committee Interaction
- Identify and Resolve Non-NELAC State Concerns

# Improving the Report Card Consistency

- ▶ Communicate Internal State Questions to all AA's
- ▶ Promote Interaction between Assessors (not just Lead Assessors)
- ▶ Devise Flexible, Workable Solutions

# Improving the Report Card Commitment

- ▶ Communicate Successes
- ▶ Emphasize Partnerships
- ▶ Active Recruitment
- ▶ Keep NELAC Open

# Critical Concerns

More at 3:00

# NELAC 7i Expectations

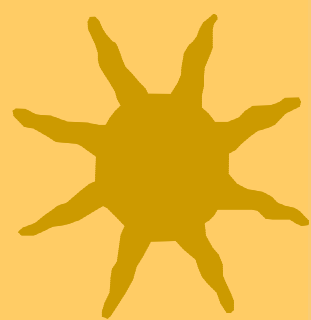
- ▶ Continue Improving :
  - Standards
  - System
- ▶ Consider the Facts
- ▶ Offer Solutions
- ▶ Voice Concerns
- ▶ Provide Input

# We Can do It!



**OPENING PLENARY**  
**EPA ACTIVITIES ON LABORATORY QUALITY SYSTEMS**

**NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE**  
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# *EPA Activities on Laboratory Quality Systems*

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Nancy W. Wentworth  
Director, Quality Staff  
Office of Environmental Information







# *Topics for Discussion*

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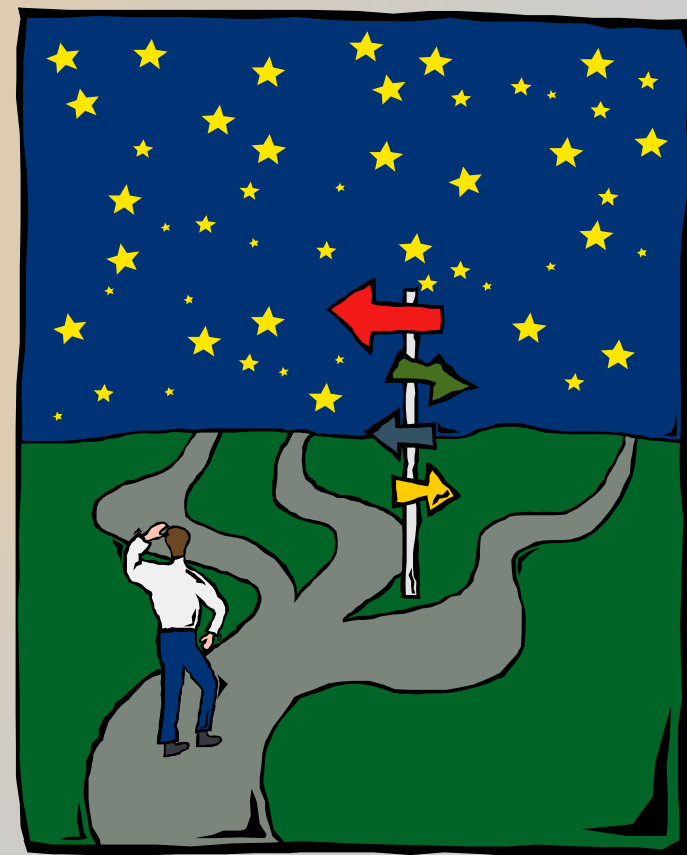
- ★ **Where are we?**
- ★ **Why do we care?**
- ★ **Where do we want to be?**
- ★ **How will we get there?**
- ★ **How will we know  
we are there?**





# *Where Are We?*

- ★ Depends on who you ask –
- ★ Office of Inspector General believes laboratory data quality is a major management challenge to the Agency





## *More . . . Where Are We?*

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- ★ **Office of Inspector General writings –**
  - **Laboratory Fraud: Deterrence and Detection, June 1999**
    - **Suggestions to Deputy Administrator**
  - **Open letter to the environmental analytical laboratory community, September 2001**
    - **“Heads up” to all laboratories that unethical practices will not be tolerated**
  - **[www.epa.gov/oigearth](http://www.epa.gov/oigearth)**





## *More . . Where Are We?*

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- ★ **Increasing numbers of investigations of laboratories by EPA and others**
- ★ **Increasing suspicion about data quality, integrity, and authenticity**
- ★ **Concerns about ability of assessments to detect vulnerabilities in quality systems and operating systems in laboratories**
- ★ **NELAC has included language on ethics in Chapter 5, Quality Systems, and will be looking at proposal for additional language at this meeting**



# *Why Do We Care?*

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★ **We use these data to make decisions that can have a direct affect on human health and the environment**



★ **We hate wasting time and money**

- **Laboratory resources**

- **Client resources**

- **Federal Agency resources**





## *More . . . Why Do We Care?*

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★ If data quality/integrity at a laboratory is questioned,

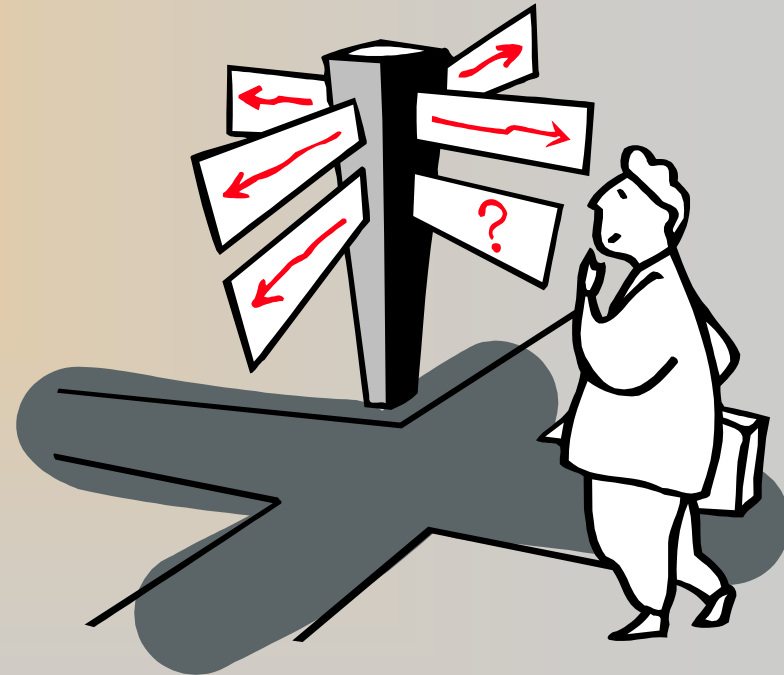
- Affected clients need to be notified
- All the data from the laboratory may need to be located and evaluated for contribution to decision – false negatives in particular
- Investigation may begin
- All this costs time, money, and adrenalin





# *Where Do We WANT To Be?*

- ★ We want to have environmental data of appropriate, known, and documented quality to support decisions
  - Efficient resource use across all environmental programs





# *How Will We Get There?*

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## **★ Cooperation across all involved sectors**

- Federal partners**
- State, local, and Tribal partners**
- Commercial laboratories**
- Private laboratories**
- Equipment designers and manufacturers**
- Interested consultants**
- Data Users**





# *More How Will We Get There?*

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- ★ **EPA Activities – different organizations have different responsibilities**
  - **Quality Staff**
    - **Developing training material for laboratory assessors on identifying weaknesses in systems and operations that could open the door to misconduct or unethical behaviors – Send me your examples, good and bad, of assessments**
    - **Continuing guidance development – verification and validation (including data integrity), data quality indicators**



# *More How Will We Get There?*

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- ★ Office of Grants and Debarment – suspension and debarment
- ★ Office of Inspector General and Office of Enforcement and Compliance Assurance -- investigations and prosecutions



# *More How Will We Get There?*

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## **★ Program Offices**

- Should require monitoring and testing that can reasonably be expected to “work”
- Should not set expectations for monitoring that require “research laboratories” not production analytical operations





# *More How Do We Get There?*

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## **★ Laboratory Community**

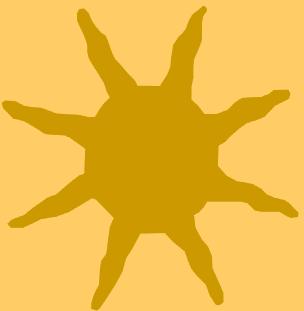
- Document the systems, and then use them, including ethics training and statements
- If the work cannot be done, then don't bid on it unless reasonable expectations can be established
- Don't take shortcuts – once you are the slippery slope, its hard to get off without getting hurt



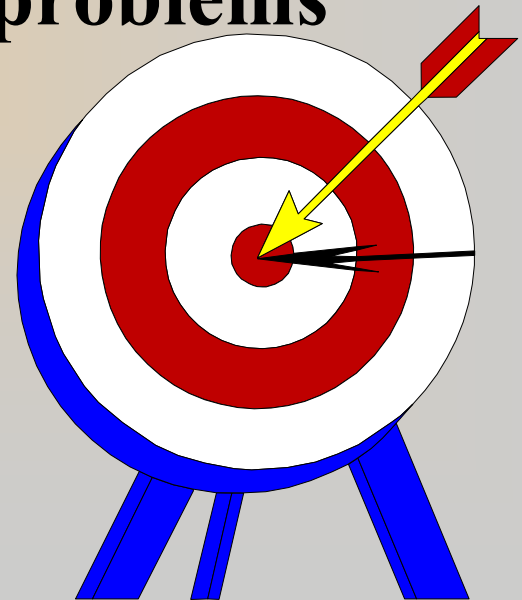


# *How Will We Know We Are There?*

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- ★ **Data, with appropriate pedigree, are readily available at a reasonable price**
- ★ **Assessments don't find problems because there Are NO problems**
- ★ **There will always be room for improvement**





# *Have Examples To Share?*

★ Please send examples of case studies or ethical dilemmas, assessments, ethics statements and policies, effective practices, etc. that can be used by others to:

**[quality@epa.gov](mailto:quality@epa.gov)**



**OPENING PLENARY  
ACCREDITING AUTHORITY WORK GROUP REPORT**

**NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE  
SEVENTH INTERIM MEETING  
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# **ACCREDITING AUTHORITY WORK GROUP AS OF DECEMBER 2, 2001**

- **FIRST MEETING JULY 19, 1999**

- **BI-WEEKLY TELECONFERENCES**

- **CURRENTLY 11 STATES AND 12 AGENCIES**

CALIFORNIA

FLORIDA

OREGON

UTAH

NEW JERSEY

NEW YORK

ILLINOIS

KANSAS

NEW HAMPSHIRE

LOUISIANA\*

PENNSYLVANIA

\*2 AGENCIES



# **ISSUES ADDRESSED & FORWARDED TO NELAC STANDING COMMITTEES**

- **ON-SITE ASSESSMENT CONSISTENCY ISSUES**
  - AA SUB-WORKGROUP ESTABLISHED TO PREPARE DRAFT SOP.
  - DRAFT SOP TO ON-SITE ASSESSMENT COMMITTEE IN NOV 2001.
  
- **RCRA WATER PT SAMPLES**
  - REQUEST TO PT COMMITTEE ASKING FOR PREPARATION OF A TABLE OF ACCEPTANCE CRITERIA FOR RCRA WATER PT SAMPLES.
  - ALSO, REQUEST TO ADD FOOTNOTE TO INDICATE THAT CURRENT CWA PT SAMPLES CAN BE USED FOR RCRA WATER SAMPLES.
  - ALSO, FOR SOIL SAMPLES THE SOIL PT WILL MEET REQUIREMENTS FOR AQUEOUS RCRA PT.



# **ISSUES ADDRESSED & FORWARDED TO NELAP STANDING COMMITTEES (CONT.)**

- **FREQUENCY & QUANTITY OF PTs**
  - ISSUES ADDRESSED BUT NO COMMON OPINION ABLE TO BE ACCEPTED BY WORKGROUP.
  - OPTIONS WILL BE PRESENTED TO PT COMMITTEE AT INTERIM CONFERENCE.
- **PT FIELDS OF TESTING**
  - LETTER TO PT PROVIDERS REQUESTING INFORMATION RELATING TO PTs AVAILABLE IN ADDITION TO NELAC PT FIELDS OF TESTING.
  - INFORMATION TO PT STANDING COMMITTEE TO REVISE NELAC PT FIELDS OF TESTING.



# **ISSUES ADDRESSED & FORWARDED TO NELAP STANDING COMMITTEES (CONT.)**

- **CHLORINE CHECK ON MICRO SAMPLES**
  - DO LABS CHECK FOR CHLORINE IN EVERY MICRO SAMPLE CONTAINER?
  - NO CONSISTENT ANSWER AMONG AAs.
  - PRESENT TO QUALITY SYSTEMS COMMITTEE AT INTERIM MEETING.



# **ISSUES ADDRESSED & POLICY ADOPTED**

- **ON-SITE ASSESSMENT CONSISTENCY**
  - AAs WILL ATTEND ON-SITE AUDITS W/ OTHER AAs.
  - TWO PRIMARY AAs FOR A GIVEN LAB WILL ATTEND ON-SITE AUDIT TOGETHER, WHEN ECONOMICALLY FEASIBLE.
  - AAs WILL SHARE AUDIT SCHEDULES THRU E-MAIL.
  - AAs WILL SHARE AUDIT REPORTS.
- **ADDITIONAL INFORMATION REQUESTED BY SECONDARY AAs**
  - MUST REMAIN BECAUSE OF INDIVIDUAL STATE STATUTORY & ADMINISTRATIVE CODE REQUIREMENTS.



## ISSUES ADDRESSED & POLICY ADOPTED (CONT.)

- **PT PROVIDERS & ANALYSIS OF QUALITY CONTROL STANDARDS**
  - STATEMENT INCLUDED IN PT INSTRUCTIONS: “IN ORDER TO INCREASE YOUR CHANCES OF PASSING, WE SUGGEST ANALYZING A QUALITY CONTROL STANDARD AT A CONCENTRATION SIMILAR TO THIS WATER SUPPLY NUTRIENTS PT STANDARD AND APPLYING CONTROL LIMITS BASED ON THE RANGES GIVEN ABOVE.”
  - LETTER TO PT PROVIDERS STATING THAT THIS PRACTICE IS UNACCEPTABLE AS IT IS CONTRARY TO NELAC STANDARDS.



# **ISSUES ADDRESSED & POLICY ADOPTED (CONT.)**

- **IDENTIFICATION OF PRIMARY AND SECONDARY ACCREDITATION ON NELAP CERTIFICATES**
  - AAs AGREED TO CLEARLY NOTE STATUS ON PAPERWORK ISSUED.



# **ISSUES UNANIMOUSLY AGREED UPON AMONGST AAs DURING TELECONFERENCES**

- **EARLY ADJOURNMENT OF TELECONFERENCES**
- **SKIPPING OF TELECONFERENCES**
- **ASSIGNING KEN JACKSON TO ALL EXTRA ACITIVITIES  
(EXCEPT KEN)**